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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/614,685

07/03/2003

Yehoshua Shachar

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7408

20995

7590

10/12/2006

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EXAMINER

GILBERT, ANDREW M

ART UNIT

PAPER NUMBER

3767

DATE MAILED: 10/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/614,685	<b>Applicant(s)</b> SHACHAR, YEHOASHUA	
	<b>Examiner</b> Andrew M. Gilbert	<b>Art Unit</b> 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2006.
- 2a) ☐ This action is FINAL.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-64 is/are pending in the application.
- 4a) Of the above claim(s) 6-32, 34-39 and 41-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5, 33 and 40 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 July 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Claims 6-32, 34-39, 41-64 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 8/3/2006.
2. Applicant's election without traverse of Apparatus Species II: claims 1-5 and Communication Species I: 33 and 40 in the reply filed on 8/3/2006 is acknowledged. Additionally, the Examiner agrees with the Applicant that claim 1 is generic.
3. Thus, claims 1-5, 33 and 40 are pending for examination.

### ***Drawings***

4. The drawings are objected to because Figures 3, 6g-6i, and 7-8 are photographs with poor quality wherein the invention cannot be distinguished from the photographs; numbers and reference characters are not plain and legible, and lines numbers and letters are not uniformly thick and well defined. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the

Art Unit: 3767

several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

### ***Specification***

5. The disclosure is objected to because of the following informalities: On pg 11, In 13, the specification reads "Ahe", wherein the Examiner believes the specification should read "The".

Appropriate correction is required.

6. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Apparatus for piezoelectric layer-wise pump and valve for use in local administration of biological response modifiers and therapeutic agents.

### ***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 3767

8. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Regarding claim 3, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention.

See MPEP § 2173.05(d).

10. Regarding claim 3, claim 3 recites the limitation "comprising:" on ln 3. This appears to indicate that further limitations are supposed to be included in claim 3; however, no such limitations are present.

11. The Examiner further notes that the Applicant has recited very broad claim limitations and the Examiner strongly suggests incorporating structural recitations of the Applicant's invention into the claims.

### ***Claim Rejections - 35 USC § 102***

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

13. Claims 1-5, 33, and 40 rejected under 35 U.S.C. 102(b) as being anticipated by Kaiser (5569187). Kaiser discloses an apparatus for infusing a medicating agent to a

Art Unit: 3767

specific desired location such as tumor, within a patient's body, comprising: a pouch (12) having one or more chambers; at least one medicating agent disposed in said one or more chambers (12); and at least one piezoelectric pump (10; col 3, lns 38-51) configured to transfer said at least one medicating agent to said patient; further comprising control logic to control said at least one piezoelectric valve to provide proper dosing and scheduling of said medicating agent (col 3, lns 19-26; col 3, lns 52-col 4, ln 6; col 5, lns 7-col 26; col 6, lns 1-3, lns 33-53; Figs 1-5); further comprising control logic to control said at least one piezoelectric valve to provide for infusing said medicating agent to a specific desired location such as tumor (col 3, lns 19-26; col 3, lns 52-col 4, ln 6; col 5, lns 7-col 26; col 6, lns 1-3, lns 33-53; Figs 1-5; wherein the Examiner notes that the apparatus is fully capable of acting on a specific desired location being a tumor); comprising control logic to control said at least one piezoelectric valve to provide for regulating, controlling, and modulating a combination therapy of cytokine and chemotherapeutic agents (col 3, lns 19-26; col 3, lns 52-col 4, ln 6; col 5, lns 7-col 26; col 6, lns 1-3, lns 33-53; Figs 1-5; wherein the Examiner notes the apparatus has control logic fully capable of controlling cytokine and chemotherapeutic agents) for the purpose of tumor elimination; further comprising control logic to control said at least one piezoelectric valve to administer less than the maximum tolerated dose of said medicating agent (col 3, lns 19-26; col 3, lns 52-col 4, ln 6; col 5, lns 7-col 26; col 6, lns 1-3, lns 33-53; Figs 1-5); and further comprising a bidirectional communication link configured to provide wireless communication (Fig 1-2; col 4, lns 55-64) to an external user.

Art Unit: 3767

14. Claims 1-5, 33, and 40 rejected under 35 U.S.C. 102(e) as being anticipated by Connelly et al (6589229). Connelly et al discloses an apparatus for infusing a medicating agent to a specific desired location such as tumor, within a patient's body, comprising: a pouch (32) having one or more chambers; at least one medicating agent disposed in said one or more chambers (32); and at least one piezoelectric pump (36) configured to transfer said at least one medicating agent to said patient; further comprising control logic to control said at least one piezoelectric valve to provide proper dosing and scheduling of said medicating agent (col 7, lns 46-col 8, lns 29; col 8, lns 56-col 9, lns 34; Summary); further comprising control logic to control said at least one piezoelectric valve to provide for infusing said medicating agent to a specific desired location such as tumor (col 7, lns 46-col 8, lns 29; col 8, lns 56-col 9, lns 34; Summary); wherein the Examiner notes the apparatus is fully capable of medicating a specific target in the body); comprising control logic to control said at least one piezoelectric valve to provide for regulating, controlling, and modulating a combination therapy of cytokine and chemotherapeutic agents (col 7, lns 46-col 8, lns 29; col 8, lns 56-col 9, lns 34; Summary; wherein the apparatus is fully capable of cytokine and chemotherapeutic agents) for the purpose of tumor elimination; further comprising control logic to control said at least one piezoelectric valve to administer less than the maximum tolerated dose of said medicating agent (col 7, lns 46-col 8, lns 29; col 8, lns 56-col 9, lns 34; Summary); and further comprising a bidirectional communication link configured to provide wireless communication (Fig 21-22; col 9, lns 17-34) to an external user.

Art Unit: 3767

15. Claims 1-5 rejected under 35 U.S.C. 102(e) as being anticipated by Gillis et al (2003/0069541). Gillis et al discloses an apparatus for infusing a medicating agent to a specific desired location such as tumor, within a patient's body, comprising: a pouch (74) having one or more chambers; at least one medicating agent disposed in said one or more chambers (74); and at least one piezoelectric pump ([00124]) configured to transfer said at least one medicating agent to said patient; further comprising control logic to control said at least one piezoelectric valve to provide proper dosing and scheduling of said medicating agent ([0069]); further comprising control logic to control said at least one piezoelectric valve to provide for infusing said medicating agent to a specific desired location such as tumor ([0070], [0100]); comprising control logic to control said at least one piezoelectric valve to provide for regulating, controlling, and modulating a combination therapy of cytokine and chemotherapeutic agents ([0005], [0077]) for the purpose of tumor elimination; further comprising control logic to control said at least one piezoelectric valve to administer less than the maximum tolerated dose of said medicating agent ([0069], [0119]-[0130]).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew M. Gilbert whose telephone number is (571) 272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.



Art Unit: 3767

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Andrew Gilbert

KEVIN C. SIRMONS  
SUPERVISORY PATENT EXAMINER  
